
An Analysis and Evaluation of
Certificate of Need Regulation in Maryland

Cardiac Surgery and Therapeutic Catheterization Services

*Response to Written Comments on the
Staff Recommendations*

MARYLAND HEALTH CARE COMMISSION

November 21, 2000

An Analysis and Evaluation of Certificate of Need Regulation in Maryland: Cardiac Surgery and Therapeutic Catheterization Services

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I. Introduction

During the 1999 session, the Maryland General Assembly passed House Bill 995, entitled *Health Care Regulatory Reform – Commission Consolidation (Chapter 702, Acts 1999)*. Regulatory responsibilities and duties of the Maryland Health Care Access and Cost Commission and the Maryland Health Resources Planning Commission were consolidated, integrated, and streamlined under the Maryland Health Care Commission. Uncodified language in Section 11 of the bill required the Maryland Health Care Commission to examine the certificate of need (CON) process.

The staff of the Commission prepared the *Working Paper: Cardiac Surgery and Therapeutic Catheterization Services* as the basis for public comment on whether changes are needed with respect to the CON regulation of cardiovascular services in Maryland. The current CON program regulates the availability, accessibility, cost, and quality of cardiovascular services. The *Working Paper* presented several options for addressing those characteristics. Key regulatory aspects of each option are listed below.

- A. Retain current CON authority
 - CON for new open heart surgery (OHS) service
 - CON regulation of therapeutic catheterization through on-site OHS backup
 - CON approval based on State plan and CON criteria, adopted as regulations
 - CON withdrawal for failure to comply with conditions of approval
- B. Strengthen CON regulation
 - CON for new diagnostic or therapeutic cardiac catheterization service
 - Public notification of violation of CON or enforcement
 - Monetary penalties for failure to comply with CON conditions
- C. Restrict CON regulation
 - CON and plan limited to availability and geographic accessibility
 - Elimination of CON authority to regulate quality or financial access
- D. Eliminate CON regulation
 - No CON for new open heart surgery service
 - State health plan for assessment of geographic access
 - Collection and analysis of data
 - System for measuring performance of hospitals

The Commission released the *Working Paper* on August 18, 2000, and invited interested organizations and individuals to submit written comments until September 18, 2000. The Commission received comments from 15 organizations.

At a public meeting on October 25, 2000, the Commission's staff presented the public comments on the *Working Paper*. Comments supporting the elimination of CON regulation suggested licensure with performance standards as an additional option and the preferred alternative to CON.

Instead of wholesale change in the authority of the CON program, the staff recommended a number of administrative changes that the Commission can undertake under its current statutory authority. The staff also recommended an expansion of the sanctions available to the Commission to encourage quality of care, which will require a statutory change. A list of the staff recommendations follows.

1. The Commission should establish an Advisory Committee on Outcome Assessment in Cardiovascular Care to review available models and recommend an ongoing process to assess outcomes of cardiovascular care.
2. The Commission should use a well-designed research project to investigate cardiac surgical support for specific groups of patients receiving elective angioplasty.
3. The Commission should continue to coordinate its activities with other entities. The MHCC and HSCRC should monitor changes in market demand and referral patterns as a result of new or expanded open heart surgery services that may affect Maryland's Medicare waiver.
4. The Commission should continue its oversight of the availability, accessibility, cost, and quality of cardiac surgery services through the CON program, including the adoption of quality standards for cardiac surgery programs.
5. The Commission should withdraw the CON and authority to operate a new or existing cardiac surgery program for failure to meet adopted standards for quality of care within a specified period.

The Commission invited interested organizations and individuals to submit written comments on *An Analysis and Evaluation of Certificate of Need in Maryland: Cardiac Surgery and Therapeutic Catheterization Services – Summary of Public Comments and Staff Recommendations* until November 8, 2000. The Commission received comments from the following:

Adventist HealthCare, Inc.
Dimensions Healthcare Systems, Inc.
Greater Baltimore Medical Center
MedStar Health, Inc.

II. Summary of the Public Comments on the Staff Recommendations

Written comments on the recommendations in *An Analysis and Evaluation of Certificate of Need in Maryland: Cardiac Surgery and Therapeutic Catheterization Services – Summary of Public Comments and Staff Recommendations* are summarized below. Copies of the full text of the public comments are available from the Commission upon request.

Recommendation 1. Advisory Committee on Outcome Assessment in Cardiovascular Care

Oppose. Dimensions Healthcare Systems strongly opposed the establishment of standards relating to quality to be adopted by the Commission and used to revoke the CON of entities not meeting the quality standards. Dimensions stated that there are no indications that any hospital has unacceptable morbidity or mortality problems. Cardiac surgery, like all hospital services, is already tightly regulated from a qualitative perspective by the Office of Licensing and Certification Services

(Office of Health Care Quality, or OHCQ), by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and by the ongoing risk of malpractice litigation.

Dimensions suggested that a more appropriate model for the improvement of quality is the Northern New England Cardiovascular Disease Study Group, which collects data and monitors quality on a voluntary basis among hospitals in Maine, New Hampshire and Vermont. The process of continuous quality improvement is collaborative and non-punitive. Because it does not need to adopt its standards as a regulation, the program is flexible and can change its standards. A vehicle to replicate this program in Maryland already exists in the form of the Quality Indicators Project being conducted by the Maryland Hospital Association. The staff's proposal should be altered to recommend the formation of a similar program in Maryland under the auspices of the Maryland Hospital Association or similar body.

MedStar Health also supported a collaborative, regional approach modeled after the New England Cooperative. The providers should manage the Cooperative. Collaboration with the Commission will be useful, but an additional regulatory/oversight body is not needed.

Support. Adventist HealthCare supported the recommended change within the existing authority of the MHCC.

Recommendation 2. Research project on cardiac surgical support for elective angioplasty

Support. Adventist HealthCare supported the recommended change within the Commission's existing authority. Dimensions Healthcare Systems also supported the staff's recommendation.

MedStar Health suggested that clinical research by the medical community should inform the Commission in its efforts. The Commission should monitor, encourage and use the results of such research. Before the Commission directly, by itself or through agents, sponsors clinical research, broader discussion should take place with those who would be the primary investigators and institutional sponsors, and those who would collect, evaluate and publish the relevant data. MedStar also raised such issues as whether State-sponsored research has special liability protections for the participating agencies.

Recommendation 3. Interagency monitoring of impact on Medicare waiver

Support. Adventist HealthCare supported the proposal of the staff. Dimensions Healthcare Systems also supported the staff's recommendation.

Recommendation 4. Continued CON oversight including adoption of standards for quality

Oppose. The Greater Baltimore Medical Center (GBMC) expressed the belief that the current CON restrictions prevent many of the State's largest and best equipped hospitals from providing the best possible care to heart disease patients. GBMC stated that the patient and his/her physician should determine where patients receive health care, not a CON process that has as its goal limiting access. A system should permit hospitals with a proven capability of providing a full spectrum of cardiac care to offer those services to patients who choose to go there, subject to any ongoing quality of care restrictions that the State chooses to impose. GBMC supported the use of licensure to fully replace certificate of need to determine the ability of hospitals to offer open heart surgery and PTCA.

Support. Adventist HealthCare supported the recommendation, stating that the current checks and balances of planning and regulation should remain in effect in Maryland as long as the incentives for duplication and unnecessary care are present in the health care delivery system. Dimensions Healthcare Systems also supported the staff's recommendation.

Recommendation 5. Authority to withdraw CON of new and existing programs

Oppose. Adventist HealthCare drew a distinction between promoting quality of care for cardiac patients in the health care system, the role of the CON program as currently authorized, and policing the quality of care patients actually receive in existing programs, which is performed by the Office of Health Care Quality. In the view of Adventist HealthCare, there is a potential conflict with the MHCC being authorized to close programs at the same time as it retains CON authority to approve new ones. The MHCC plays an important role in ensuring the quality of care, but should not do so in the manner recommended.

Dimensions Healthcare Systems strongly opposed the recommended legislative change. Dimensions noted that even if the legislature were to adopt such legislation, the application of this authority on an *ex post facto* basis to an existing cardiac surgery program would likely be challenged on constitutional grounds. Furthermore, the recommendation would require that the legislature give the MHCC additional procedural powers which it has not historically had. As an example, the Commission will have to have the companion authority to issue subpoenas, to conduct licensing hearings, to hire investigators or retain experts in order to perform its new role. Dimensions also questioned limiting such authority to a service in which there is no identified quality problem.

While supporting the CON process as a general matter, MedStar Health disagreed with the Commission taking on overlapping authority with the Office of Health Care Quality, which has the authority, staff and enforcement tools to address quality of care issues. Without teams of surveyors actually evaluating care rendered in programs, decisions about quality issues would inappropriately be made based on statistical data alone. Also, with only the authority to permit programs to remain open or to close, the Commission would lack the tools of other enforcement agencies to evaluate, monitor and apply remedies and sanctions incrementally to address quality issues. The Commission should inform and contribute to the work of other agencies such as the OHCQ, not supplement or overlap it.

MedStar also commented that the authority to close an OHS program based on quality of care enforcement will require the adoption of substantial due process guarantees and procedures for those affected facilities and communities they serve. Important questions will arise, such as whether other providers without OHS programs will be permitted to intervene as interested parties during a hearing to revoke the CON of an existing provider.

Support. None of the written comments supported granting the Commission the authority to revoke the CON of existing and new programs that fail to meet quality standards to be adopted by the Commission.

III. Staff Response and Recommended Action

Limiting access to care has never been a goal of the CON program under Federal or State legislation. On the contrary, achieving equal access to quality health care at a reasonable cost has been, and remains, a priority of the program in Maryland. There is evidence that most residents now have reasonable geographic access to more than three hospitals with cardiac surgery services. The

actual choice among available programs remains between the patient and physician, although the payer may influence where the patient receives care.

With regard to the quality of cardiovascular care, earlier comments on the *Working Paper* pointed out that the Office of Health Care Quality does not routinely survey acute hospital services. Under the current deeming provision of State law, the licensing authority generally cedes its review function to the Joint Commission on Accreditation of Healthcare Organizations, a private standards organization.

The staff is aware that, like the Department of Health and Mental Hygiene, the Commission may not duplicate standards or requirements related to quality that national accrediting organizations such as the JCAHO have adopted and enforced. The staff recommendation does not propose to do so.

The comments suggest a voluntary approach to collecting data and monitoring quality, similar to the Northern New England Cardiovascular Disease Study Group (NNECDSG). It should be noted that the stimulus for establishing the NNECDSG in 1987 was Medicare data, published by the Health Care Financing Administration, showing institutional differences in mortality rates. The group's own study of in-hospital mortality rates associated with coronary artery bypass surgery also found substantial variation among institutions and surgeons in the region, and the differences were not solely the result of differences in case mix.

The Northern New England Cardiovascular Disease Study Group reflects a shift from competition to clinical collaboration in an effort to improve care. Members of the voluntary consortium share data and experience about managing cardiovascular disease. All specific data showing comparisons of outcomes among the hospitals and physicians are kept confidential. Nevertheless, adoption of this particular approach has been slow in other areas of the nation.

The Quality Indicator Project of the Association of Maryland Hospitals and Health Systems has been described as a vehicle to replicate the consortium in Maryland. The Quality Indicator Project includes a variety of measures for acute care. Participation in the project is voluntary, and each facility decides which measures of performance to use.

As part of the development of report cards for hospitals, the Commission has considered the Quality Indicator Project as well as other systems of measurement. The Commission is required to establish a system to comparatively evaluate the outcomes and performance of hospitals. The purpose of the system is to improve the quality of care through the dissemination of findings to the hospitals, consumers, and interested parties. Models that rely on voluntary participation or restrict access to needed data, however, may limit the Commission's effectiveness in performing a number of its statutory duties.

New Jersey, Pennsylvania, and New York offer examples of one regulatory approach. The State collects data from each hospital providing cardiovascular services, analyzes the data, and makes specific data available to the public in addition to providing feedback to the hospitals. An advisory panel works collaboratively with each State. Like the voluntary consortium, this approach has received national recognition, but limited replication.

Elements of both approaches have helped to improve the outcomes of cardiovascular care. They need not be mutually exclusive. Before the Commission adopts standards or sponsors clinical research related to quality, the advisory committee will provide a forum for the broader discussion suggested by the comments. Institutions and practitioners will continue to have opportunities to collaborate regionally, for example, by sharing information about best practices.

Maryland law gives the Commission the authority to grant certificates of need. When applying for a CON, an applicant makes a representation to the Commission that the service will meet certain standards when it becomes operational. The Commission should have the authority to monitor the compliance of a service and revoke the “operating certification” of the service if the Commission determines that revocation is an appropriate sanction. Both Federal and State legal standards, including the Commission’s own regulations, already govern many aspects of the Commission’s conduct toward CON applicants, protecting the applicants from any arbitrary action. The Commission would continue to provide due process under the new authority recommended by the staff.

It should be noted that the periodic review of existing services is not a new proposal. Federal legislation establishing the State health plan and CON program included a third function that was referred to as appropriateness review. This function evolved from an original concept of periodic recertification, to periodic determination of the continuing need for a service, to periodic review of appropriateness. The public finding of appropriateness or inappropriateness was to be based on established criteria that included need, availability and accessibility, financial viability, cost effectiveness, and quality. The law did not require States to apply sanctions, although there were potential indirect sanctions associated with making findings available to the public.

The certificate of need program does not operate in isolation. The staff agrees that the Commission should inform and contribute to the work of other agencies such as the OHCQ. For example, the agencies should share the results of statistical analyses and investigations of individual complaints. The comments raise important issues that must be addressed as the recommendations are implemented. The Commission will continue to recognize health care providers, consumers, and payers as important participants in any health care delivery system and encourage their active participation in the development and implementation of health policy.

The staff recommends that the Commission approve Recommendations 1 through 4 as proposed in *An Analysis and Evaluation of Certificate of Need in Maryland: Cardiac Surgery and Therapeutic Catheterization Services – Summary of Public Comments and Staff Recommendations*. **The staff recommends that the Commission approve a revision of Recommendation 5** as follows.

Recommendation 5. The Commission should have the authority to revoke its certification if an operating service fails to meet the standards adopted by the Commission. The Commission should conduct a study before seeking the required statutory change.

When applying for a CON, an applicant makes a representation to the Commission that the service will meet certain standards when it becomes operational. If a service fails to meet the standards, the service should be given a period of time to remedy the failure. If the noncompliance continues after the period for remedy, the Commission should withdraw its certification and the authority to operate the service. Before seeking the necessary change in its statute, the Commission should examine the effectiveness of existing monitoring systems, assess the extent of noncompliance, review past remedial action or enforcement of sanctions, and address other issues, such as shared responsibilities and workload. This study should begin after completion of the current two-year study and include all services covered by the certificate of need program.